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Yasunori Shiraki

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10/27/2010

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.

P.O. BOX 2902

MINNEAPOLIS, MN 55402-0902

EXAMINER

DINH, BACH T

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/537,708	<b>Applicant(s)</b> SHIRAKI ET AL.	
	<b>Examiner</b> BACH T. DINH	<b>Art Unit</b> 1795	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 14-17, 19 and 21-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12, 14-17, 19 and 21-23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Summary***

1. This is the response to the communication filed on 08/13/2010.
2. Claims 1-12, 14-17, 19 and 21-23 remain pending in the application.
3. The application is not in condition for allowance.

### ***Claim Objections***

4. Claim 1 is objected to because of the following informalities: on line 27, between "end edge of the substrate, and" and "third main line", the letter "a" is believed to be missing.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12, 14-17, 19 and 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The amended claim 1 recites that "a second main line portion extending from the first main line portion toward the second longitudinal edge of the substrate along the second end edge" (emphasis added), which implies that the second main line portion is situated at the second end edge. The amended claim 1 further recites "third main line portion extending from the second main line portion" (emphasis added), which resides at the second end edge, "toward the second end edge of the substrate" (emphasis added); it is unclear as to how the

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third main line portion that extends from the second main line portion, which resides at the second end edge, toward the same second end edge (emphasis added). Thus, claim 1 and its dependent claims are rejected as being indefinite.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawanaka et al. (WO 99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) with further evidence provided by Oura et al. (US 2006/0042942) and Neel et al. (US 6,743,635).

Independent claim 1 recites "an analytical tool to be mounted to an analytical apparatus" and subsequent dependent claims recite "the analytical tool". Therefore, patentability of the analytical tool is determined based on the structure of the analytical tool itself and not the way in which the analytical tool is mounted to the analytical apparatus or the structures of the analytical apparatus or the effects on the analytical tool when the analytical tool is mounted to the analytical apparatus.

Addressing claim 1, Kawanaka discloses an analytical tool, comprising:

A substrate 10 (figure 6 included below) including a first end edge (as indicated below) and a second end edge (as indicated below) opposite each other;

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Electrodes 146 and 117 extending between the first and second edges;

A reagent portion 147 formed on the substrate adjacent to the first end edge (front end edge);

Kawanaka further discloses the electrode 146 is a negative terminal (13:1-8) which is connected to the counter electrode (10:28-34) and the electrode 117 is the positive terminal which is connected to the measuring electrode (10:28-34). Moreover, the terminal 146 is grounded via the electrodes 104 and 103 when the test strip is connected to the apparatus 131 (13:26-34, figure 4);

Neel discloses a grounded counter electrode also discharge stored charges (14:60-62).

The evidence provided by Neel shows that the grounded counter electrode 146 of Kawanaka is capable of functioning as the claimed disturbing-noise countermeasure electrode with the electrode 117 serving as the measuring electrode.

Oura discloses a blood glucose sensor (figure 7); wherein, the electrodes 81 and 82 are exposed in the flow channel and at the terminal ends 91 and 92, respectively (figure 7).

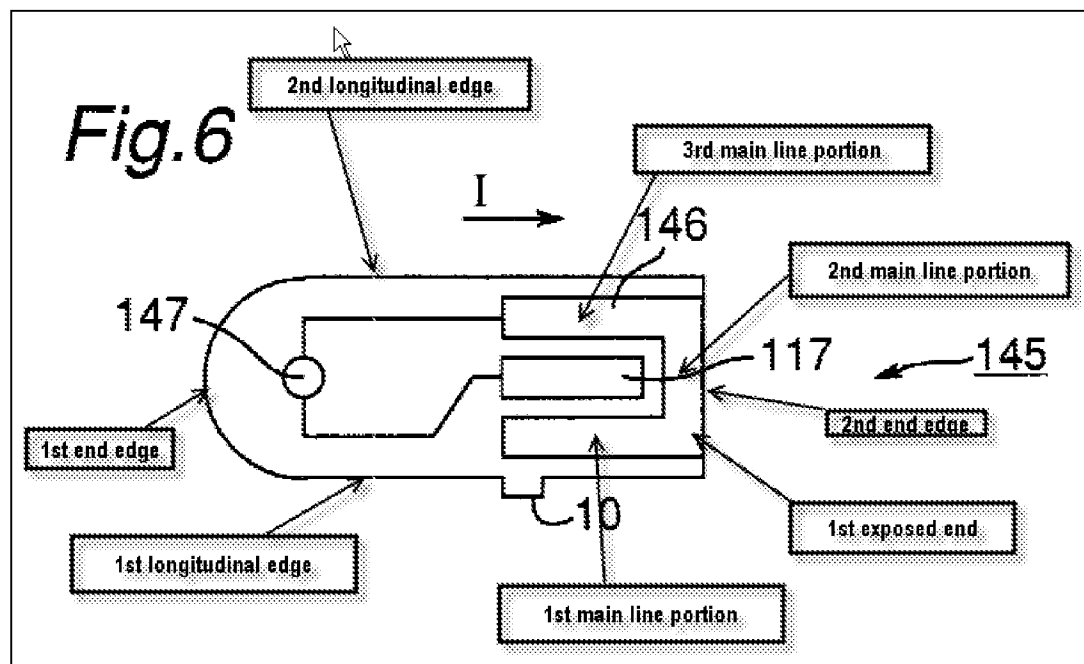
Furthermore, the exposed portion are subjected to static electricity when the test strip 8 is mounted manually into the measuring apparatus 9 [0003-0005]; therefore, in the biosensor of Oura the exposed portions of the electrodes 81, 82 in the flow channel and at the terminal ends 91 and 92 are the noise inputting exposed portion for allowing input of static electricity.

Kawanaka discloses in figures 25-28 that an insulating layer covers the electrodes except a part of the measuring and counter electrodes that are exposed to the sample solution and the terminal ends of the working and counter electrodes are also exposed (30:27-51).

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Therefore, as evidenced by Oura, the exposed portions of the counter electrode for contacting the analyte and at the terminal end are capable of allowing the input of static electricity. Hence, the exposed portions of the counter electrode are the noise inputting exposed portion of the disturbing-noise countermeasure electrode for allowing input of static electricity.

The evidence provided by Neel and Oura shows that the counter electrode of Kawanaka is structurally equivalent to the claimed disturbing-noise countermeasure electrode for the counter electrode has the exposed portions that allow the input of static electricity and is capable of discharge stored charges.



Wherein the disturbing-noise countermeasure electrode includes a first exposed end, a first main line portion and a second main line portion extending in the manner required by current claim as indicated above. With respect to the limitation regarding the third main line portion in conjunction with the indefinite rejection above, figure 6 of

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Kawanaka shows that the third main line portion is connected to the second main line portion; therefore, the third main line portion extending from the second main line portion toward the second end edge of the substrate (the third main line portion indicated above extend in all direction, including the direction of the second end edge) along the second longitudinal edge of the substrate;

Wherein the working electrode 117 includes a second exposed end located adjacent to the second end edge of the substrate (figure 6 above) and extends from the second exposed end toward the first end edge of the substrate between the first and third main line portions of the disturbing-noise countermeasure electrode (figure 6 above); and

Addressing claim 2, Kawanaka discloses the electrode 117 is the measuring electrode and the electrode 146 is the counter electrode as discussed above; therefore, the counter electrode 146 is capable of applying voltage to a target portion in cooperation with the electrode 117.

Addressing claims 3-4, the subject matter of current claims are not given weight because they are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Kawanaka discloses the electrode 146 is grounded (figure 4, 13:26-34) and when switches 132 and 133 are at the open positions

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the electrode 146 is disconnected from the analysis circuit when the analytical tool is amounted to the analytical apparatus.

9. Claims 11-12, 14-16 and 17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kawanaka et al. (US 6,599,406) with further evidence provided by Oura et al. (US 2006/0042942) and Neel et al. (US 6,743,635).

Addressing claim 11, in figure 33, Kawanaka discloses a flow path 9 and an air vent provided in the cover 8 (12:48-60, the test strip 145 has the same configuration as the test strip 1 disclosed in figure 33). Although the biosensor shown in figure 33 is labeled as prior art, it is Examiner's interpretation and position that the flow path 9 and air vent (the combination of the channel 9 and the aperture on layer 8 constitute the air vent) of figure 33 are applicable to and present in the biosensor shown in figure 6 of Kawanaka.

In the alternative, at the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor in figure 6 of Kawanaka with the flow path 9 and the air vent as shown in figure 33 because doing so would allow one to facilitate the movement of blood via the capillary action provided by the flow path 9 and the air vent 8 (Kawanaka, 1:63-2:8).

Addressing claim 12, in figure 33, Kawanaka discloses the counter electrode 6 is connected to the air vent; therefore, any disturbing noise coming through the air vent would inherently come into contact with the counter electrode. Hence, Kawanaka discloses the claimed input portion according to the claim language. Alternatively, in the



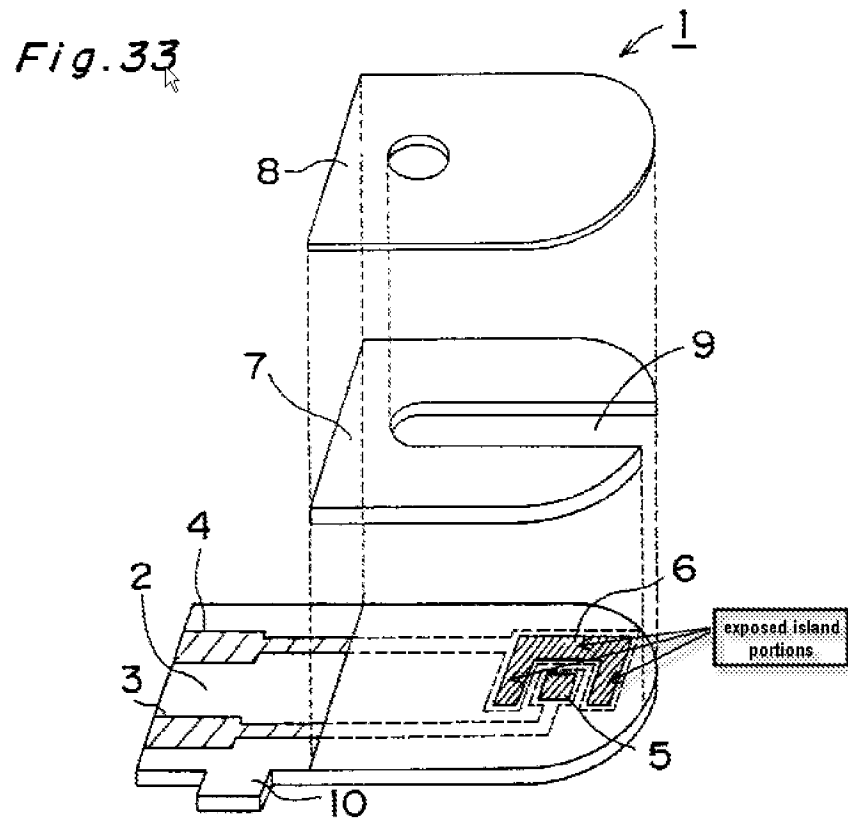
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modification discussed above, the counter electrode of the biosensor in figure 6 being connected to the air vent would inherently come into contact with any disturbing noise coming through the air vent.

Addressing claims 14-16, Kawanaka discloses the counter electrode is covered by the insulating layer except for the portion 272 where the electrode comes into contact with the analyte (30:27-36).

In figure 33, Kawanaka discloses the counter electrode 6 or the disturbing-noise countermeasure electrode further include an island provided directly below the air vent and partially covered by an insulating film (the combination of the channel 9 and the aperture of layer 8 constitute the air vent; therefore, the portions as indicated in figure 33 below are portions of the island disposed directly below the air vent and partially covered by an insulating film); wherein, the insulating film includes an opening for partially exposing the island to serve as the noise inputting exposed portion (please see figure 33 below, the exposed portion of the island are susceptible to static energy as discussed above).

With respect to the limitation of claims 15-16, the combination of layers 7 and 8 constitute the cover which is bonded to the substrate and in which the air vent is formed and the exposed portion of the counter electrode surrounds the air vent (figure 33).



Addressing claim 17, in figure 33, the counter electrode 6 surrounds the working electrode 5. Therefore, due to the fact that Kawanaka focuses more on the arrangement of the terminal ends of the electrodes, Kawanaka does not disclose in detail the arrangement of the counter electrode and the working electrode in figure 6. Therefore, it is Examiner's position that the counter electrode in figure 6 surrounds the working electrode in the manner shown in figure 33.

In the alternative, it would have been obvious for one with ordinary skill in the art to modify the biosensor of figure 6 to have the counter electrode surrounds the working electrode in the manner shown in figure 33 because doing so would allow one to obtain a

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biosensor that is still capable of measuring the concentration of glucose. Furthermore, the counter electrode of figure 33, separate or in combination, would not have performed a materially different function when surrounding the working electrode.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. Claims 5-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawanaka et al. (WO99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) in view of Neel et al. (US 6,743,635) with further evidence provided by Oura et al. (US 2006/0042942).

Addressing claims 5-10, Kawanaka discloses the plurality of electrodes include a first electrode (figure 6, the working electrode that is connected to the terminal 117) to be

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connected to the analysis circuit, a second electrode for applying voltage to a target portion 147 in cooperation with the first electrode (the counter electrode that is connected to the terminal 146). As discussed above in the rejection of claim 1, the counter electrode is capable of serving as the disturbing-noise countermeasure electrode.

Kawanaka is silent regarding a third electrode which is not involved in the voltage application to the target portion and serves as the disturbing-noise countermeasure electrode.

Neel discloses a biosensor comprises a plurality of electrodes include a first electrode 22 serving as the working electrode (5:60-64) to be connected to the analysis circuit, a second electrode 24 for applying voltage to a target portion 90 (figure 3) in cooperation with the first electrode (5:60-64, the electrode 24 is the counter electrode, for applying a voltage to the working electrode, 19:50-54). Furthermore, the biosensor includes a third electrode 30 (figures 1-3), which is not involved in the voltage application to the target portion, and wherein the third electrode serves as the disturbing-noise countermeasure electrode (15:37-39, the electrode 30 is grounded to discharge stored charges; therefore, the electrode 30 is capable of serving as the disturbing-noise countermeasure electrode, please see the rejection of claim 1 under 35 U.S.C. 102(e) in view of Neel above).

Additionally, Neel discloses the electrode 30 is grounded when being connected to the ground connection terminal 242 of the analytical apparatus (figure 18, 19:61-65).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor of Kawanaka with the fill detecting electrodes 28 and 30 of Neel because doing so would allow one to determine whether adequate sample is

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present and has mixed with the reagent layer (Neel, 5:2-26). In the modified biosensor of Kawanaka, the counter electrode and the fill-detecting electrode 30 are the second and third electrodes serve as the disturbing-noise countermeasure electrodes.

With respect to the limitations of claims 6-7 and 9-10, the subject matters of current claims are directed to the electrical connection when the analytical tool is mounted to the analytical apparatus. The analytical apparatus is only what applicant intends to mount the analytical tool to (see preamble of claim 1), so limitations drawn to how the analytical tool interacts with the unspecified and unclaimed analytical apparatus do not further define the analytical tool itself. However, Neel discloses the electrode 30 is grounded (15:37-39). Furthermore, figure 18 discloses the contact 242 is electrically connected to the electrode 30 (19:55-57); therefore, when the switch 430 is in the open position, the electrode 30 is not being electrically connected to the analytical apparatus.

13. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kawanaka et al. (WO99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) and in view of White et al. (US 5,438,271) with further evidence provided by Oura et al. (US 2006/0042942) and Neel et al. (US 6,743,635).

Addressing claim 19, Kawanaka discloses the disturbing-noise countermeasure electrode comes into contact with a corresponding one of the terminals of the analytical apparatus earlier than the other electrode 117 because the electrode 146 is located closet to the second edge as indicated above in figure 6.

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Kawanaka is silent regarding “the other electrodes” limitation for electrode 117 is the only electrode on the test strip besides the electrode 146.

White discloses a test strip 30 comprises electrodes 36 and 34 that are equivalent to the electrodes involved in the measurement of the analyte (3:15-38); therefore, the electrodes 34 and 36 are equivalent to the counter and working electrodes. The test strip 30 further comprises electrode 32 for checking the meter's measurement function (3:28-38).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the test strip of Kawanaka with the electrode 32 of White because the electrode 32 allows one to check whether the meter is malfunction or in proper working order (White, 5:64-6:15). In the modified test strip of Kawanaka, the electrode 32 would come into contact later than the counter electrode because the electrode 32 is shorter than the other electrodes as disclosed by White (figure 4).

14. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kawanaka et al. (WO99/05516) with equivalent English translation provided by Kawanaka et al. (US 6,599,406) and in view of Rappin et al. (US 6,572,745) with further evidence provided by Oura et al. (US 2006/0042942) and Neel et al. (US 6,743,635).

Addressing claim 21, Neel is silent regarding a pinch portion.

Rappin discloses a biosensor; wherein, the side of the biosensor 310 has contour portions or claimed pinch portions located at the sides of the body (figure 13, 11:45-48).

At the time of the invention, one with ordinary skill in the art would have found it obvious to modify the biosensor of Neel with the contour portions on the biosensor body

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like that of Rappin because the contour portions allow easy insertion of the biosensor to the meter (Rappin, 11:45-48).

Addressing claims 22-23, the first and second longitudinal edges of Kawanaka are shown above; furthermore, Rappin discloses the pinch portion comprises a recess formed the longitudinal edges of the substrate (figure 13). Therefore, in the modified test strip of Kawanaka, the pinch portion would also comprises the recess formed each of the first and second longitudinal edges of the substrate as required by claim 23.

Additionally, figure 6 of Kawanaka discloses the forward edge of the electrodes 117 and 146 are level with the forward edge of the projection 10 (figure 6) with the first and third main line portions extend along the first and second longitudinal edges, respectively.

Moreover, in figures 25-30, the insulating film does not cover the entire electrodes for the terminal ends of the electrodes are exposed including the portions near the first and second longitudinal edges; therefore, in the modified test strip of Kawanaka according to claim 21, the portions of the first and third main line portions not covered by the insulating film would be the noise inputting exposed portion adjacent to the pinch portion because the word "adjacent" is interpreted to include the definition of "being near or close".

### ***Response to Arguments***

15. Applicant's arguments filed 08/13/2010 have been fully considered but they are not persuasive.

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With respect to Applicant's arguments regarding the 35 U.S.C. 102(b) rejections based on the disclosure of Kawanaka, the arguments are not persuasive for the following reasons.

Firstly, Applicant's arguments regarding the test strip 141 is not germane to the content of the rejection for Examiner relied on the test strip 145 in figure 6 for the rejection.

Secondly, Applicant's argument that the test 145 is not measurable with the measuring apparatus shown in figure 4, the argument is not persuasive because Kawanaka explicitly states the test strip 145 is set to the concentration measuring apparatus 131 (12:27-52 and 13:26-34). Furthermore, the claims are directed to the analytical tool and not the combination of the analytical tool and the analytical apparatus; therefore, Applicant's arguments directed to the mounting of the analytical tool to the analytical apparatus are not germane to the content of the claim. Moreover, Kawanaka discloses the measuring apparatus 131 performs the operation one to three when the test strip 145 is inserted, including the step of grounding the electrode 146 (13:42-47), which is essential in discharging static electricity according to current application.

Thirdly, Applicant's argument regarding the test strip 145 is not for discharging static electricity is not persuasive because the argument is directed to the function of the test strip. The MPEP states that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function" and "a claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be



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employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim” (emphasis added, please see MPEP 2114). In instant situation, Kawanaka discloses the electrode having the first exposed end, the first main line portion, the second main line portion and the third main line portion as required by current claim 1; furthermore, Oura discloses that the exposed ends of the electrode are susceptible to static electricity and Neel discloses that grounding the electrode would discharge stored static electricity as discussed above. Therefore, the evidence provided by Oura and Neel show that the electrode of Kawanaka is capable of functioning as the disturbing-noise countermeasure electrode in the manner required by current claim.

For the reasons above, Examiner maintains the position that the analytical tool of claim 1 is anticipated by Kawanaka because Kawanaka discloses the test strip that comprises all the structural requirements of the claim.

With respect to Applicant’s argument of claim 14, the portion of the disturbing-noise countermeasure electrode that is the structural equivalence of the claimed island is discussed above.

Applicant’s arguments regarding the rejections of the dependent claims of claim 1 are not persuasive because the arguments regarding the rejection of claim 1 is not persuasive.

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***Conclusion***

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BACH T. DINH whose telephone number is (571)270-5118. The examiner can normally be reached on Monday-Friday EST 7:00 A.M-3:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam X. Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nam X Nguyen/  
Supervisory Patent Examiner, Art Unit 1753

BD  
10/21/2010